K072861

JUN 2 4 2008

510(k) Summary of Safety and Effectiveness

for the CeeMax Slit Lamp™ (Halogen Lamp Series/LED Illumination series)

(per 21CFR807.92)

1. SPONSOR

CeeMax Ophthalmic
Division of Achevé Technology, Inc
17100 Gillette Ave. #113
Irvine, CA 92614
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Contact Person: Jim-Son Chou, Ph.D.

2. DEVICE NAME and Classification

Proprietary Name:	CeeMax™ Slit Lamp (Halogen Lamp Series/LED Illumination series)
Common/Usual Name:	Slit Lamp
Classification Name:	AC-powered slit lamp biomicroscope
Regulation Number:	886.1850
Product Code:	HJO
Class:	II

3. PREDICATE DEVICES

(1) Reichert PSL Slit Lamp ---- FDA 510K K061330
(2) VISION-TECH YZ SLIT LAMP ---- FDA 510K K033190

4. DEVICE DESCRIPTION

The CeeMax™ Slit Lamp's (Halogen Lamp Series/LED Illumination series) with models of 801, 802, 901, 902, 801SS, 802SS, 901SS, 902SS are similar in electro-optical design, function, materials, operation, and electro-optical performance to other conventional AC-powered slit lamp biomicroscope.

5. INTENDED USE

The CeeMax™ Slit Lamp (Halogen Lamp Series/LED Illumination series) is an AC powered microscope and accessories intended for the use in the examination of the anterior eye segment, from cornea, endothelium to posterior capsule. Slit Lamp which is intended for that is used to aid the diagnosis of diseases or traumas which affect the structure or properties of the eye.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Side by Side Comparison of the CeeMax™ Slit Lamp (Halogen Lamp Series/LED Illumination series) with Predicate Devices

	Submission Device	**Predicate Device**
	CeeMax™ Slit Lamp (Halogen Lamp Series/LED Illumination series)	Slit Lamp's YZ5F (K033190) SL-15 (K061330)
Indications for Use	Same.	AC powered microscope and accessories intended for the use in the examination of the anterior eye segment, from cornea, endothelium to posterior capsule. Slit Lamp which is intended for that is used to aid the diagnosis of diseases or traumas which affect the structure or properties of the eye
Method of operation	Same as the predicate device YZ5F (K033190) table top	YZ5F (K033190) Table Top SL-15 (K061330) Hand held
Exposure parameters	The Halogen lamp exposure parameters are the same as the predicate device. The LED exposure parameters are similar to the predicate device, detailed description was also provided.	Halogen lamp: YZ5F (K033190) LED: Reichert SL-15(K061330)
Flammability	. Thermosetting phenol formaldehyde resin	. Thermosetting phenol formaldehyde resin for the

		lamp cap YZ5F (K033190)
Brightness control	From zero to full power illumination control	Same
Light source	Halogen lamp and white LED	Halogen lamp for the YZ5F (K033190) LED for the SL-15(K061330)
Beam geometry	The same as the YZ5F (K033190)	The standard slit opening range YZ5F (K033190)
Radiation safety	The Halogen lamp exposure parameters are the same as the predicate device. The LED exposure parameters are similar to the predicate device, detailed description was also provided.	Halogen lamp: YZ5F (K033190) LED: Reichert SL-15(K061330)
Optical radiation hazard	No, warning in the manual regarding the caution and particularly for the aphakic diagnostic	No
Electrical	Safety: EN(IEC) 60601-1	Safety: IEC 60601-1
Electrical	EMC: EN(IEC) 60601-1-2 EN6100-3-2 EN6100-3-3	EMC: EN(IEC) 60601-1-2
Light Output Wavelength	The Halogen Lamp emits Visible light covers 460nm to 700nm. The LED light source covers 450nm to 650nm.	The Halogen Lamp emits Visible light covers 460nm to 650nm. The LED light source covers 450nm to 650nm.
Light Source Power	Halogen: 12V, 30W LED: 12V, 10W	Halogen(Vision Tech): 12V, 30W LED(Reichert): 12V, 6W

7. PERFORMANCE TESTING

Testing provided in this premarket notification includes certifications of electrical safety, flammability, and bench test of radiation outputs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

Jim-Son Chou, Ph.D.
President
CeeMax Ophthalmic
Division of Achevé Technology, Inc
17100 Gillette Ave. #113
Irvine, CA 92614

Re: K072861
Trade/Device Name: CeeMax Slit Lamp (Halogen Lamp Series/LED Illumination Series)
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: May 22, 2008
Received: May 23, 2008

Dear Dr. Chou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 072861

Device Name: CeeMax™ Slit Lamp (Halogen Lamp Series/LED Illumination series)

Indications For Use:

The CeeMax™ slit-lamp series is an AC-powered slit-lamp biomicroscope intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

6/18/2008

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K072861